

the inactive toxin of Fraenkel-Conrat as a transport protein (which Applicants do not admit) Bizzini would suggest indiscriminately thiolating the inactive mutant toxin rather than specifically joining the drug to the light chain.

CONCLUSION

For these reasons, Applicants believe the claims are in condition for allowance, and respectfully request that the Examiner issue a Notice to that effect. As this Reply is being filed before expiration of the three-month shortened statutory deadline, no fee is believed due; however if Applicants are in error in this regard please use our Deposit Account 01-0885 for the payment of any fees so due.

Respectfully submitted,



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REJECTION UNDER 35 U.S.C. §112(2)

Claims 33-46 were rejected as allegedly vague and indefinite in the recitation of "one or more amino acid sequence mutation" in the independent claims 33, 36, and 42. Applicants respectfully traverse this rejection.

As indicated above and clarified in the current claim amendments, the pending claims are directed to compositions and methods comprising an inactivated Clostridial neurotoxin which comprises a light chain containing one or more amino acid sequence mutation as compared to the amino acid sequence of the light chain of a wild-type Clostridial neurotoxin of the same type and from the same species, wherein said light chain is inactivated by at least one said amino acid mutation and an unmodified heavy chain.

The claims are not vague or indefinite because a person of ordinary skill in the art reading these claims in light of the accompanying description would know exactly what is intended to be claimed by the present Applicants. Applicants submit that, such a person following the claim language alone, combined with the knowledge and resources possessed by the skilled worker, could make such an inactive neurotoxin by, for example random or site-directed mutagenesis techniques.

As stated by the Court of Appeals for the Federal Circuit, "if the claims, read in light of the specification[s], reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." *North American Vaccine Inc. v. American Cyanamid Co.*, 28 USPQ2d 1333, 1339 (Fed. Cir. 1993)(citations omitted). Applicants respectfully submit that such is the present case.

Similarly, in the section entitled "Clarity and Precision", the Manual of Patent Examining Procedure indicates:

When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire.

MPEP §2173.02 (emphasis in original).

Thus, although the Applicants believe that the claim terms are as apt as is possible in light of the subject matter, at the very least the claims certainly indicate the invention with a "reasonable degree of particularity and distinctness". For this reason Applicants respectfully request that the Examiner reconsider and withdraw the present rejection, and permit the claims to proceed to issue.

FORMAL DRAWINGS

The Examiner indicated that formal drawings should be submitted in accordance with the Notice of Draftsperson's Patent Drawing Review attached to Paper No. 8. Applicant submitted formal drawings on May 12, 1998; a copy of the transmittal sheet is provided herewith. While Applicants have received no indication that these formal drawings were defective, if such was these case, please so inform Applicant's representative, and a new set of formal drawings will be provided.

CONCLUSION

For the reasons given above, Applicants believe the claims are in condition for allowance, and respectfully request that the Examiner issue a Notice to that effect. As this Reply is being filed before expiration of the three-month shortened statutory deadline, no fee is believed due; however if Applicants are in error in this regard please use our Deposit Account 01-0885 for the payment of any fees so due.

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